UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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TAMARA CARTER and DAVID CARTER, Plaintiffs, v. JOHNSON & JOHNSON; ETHICON, INC.; and ETHICON LLC, Defendants.	Case No. 2:20-cv-01232-KJD-VCF ORDER

Presently before the Court is Defendant's Motion to Limit Opinions of Daniel Elliott, M.D. (#196). Plaintiffs responded in opposition (#206) and Plaintiffs replied (#219).

I. Factual and Procedural Background

This is a products liability action involving two prescription medical devices– Prolift and TVT. On July 23, 2010, at St. Rose Dominican Hospital in Las Vegas, Nevada, Dr. Gregory Hsieh implanted a Prolift device for Plaintiff Tamara Carter's ("Mrs. Carter") posterior pelvic prolapse and a TVT mid-urethral sling for Mrs. Carter's stress urinary incontinence ("SUI"). Mrs. Carter alleges that these medical devices caused her injuries, and that Defendants are liable under claims of strict liability for failure to warn and for design defect. Her husband, Plaintiff David Carter ("Mr. Carter") raises a loss of consortium claim. Additionally, Plaintiffs claim that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, and grossly negligent. Defendants ("Ethicon") deny Plaintiffs' allegations and assert that Prolift and TVT were state of the art at the time of implant, that Mrs. Carter's alleged injuries pre-dated her surgery, that Mrs. Carter assumed the risks, and that Mrs. Carter's own actions contributed to her injuries.

Dr. Daniel Elliott specializes in treating pelvic organ prolapse ("POP") and urinary incontinence. Plaintiffs have asked Dr. Elliott to provide opinions regarding the subject of female stress urinary incontinence ("SUI"), POP, the actions of Ethicon, and specifically, the characteristics of Ethicon's products, Prolift and TVT, that make them defective. Defendants

have objected to the testimony and argue that he cannot provide reliable, trustworthy, or admissible testimony about these topics.

II. Analysis

a. Legal Standard

Fed. R. Evid. 702 permits a "witness who is qualified as an expert by knowledge, skill, experience, training, or education [to] testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." The Supreme Court gave expanded direction on Rule 702 in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). In Daubert, the Court held that Rule 702 imposed "a special obligation upon a trial judge to 'ensure that any and all scientific testimony… is not only relevant, but reliable.'" See Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999). The Court expanded this gatekeeping obligation to all expert testimony. Id. at 147. Daubert "established that, faced with a proffer of expert scientific testimony, the trial judge, in making the initial determination whether to admit the evidence, must determine whether the expert's testimony reflects (1) "scientific knowledge," and (2) will assist the trier of fact to understand or determine a material fact at issue." Daubert, 509 U.S. at 592. The "focus must be solely on principles and methodology, not on the conclusions that they generate." Id. at 595.

The Ninth Circuit has emphasized that "Rule 702 is applied consistent with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barrier to opinion testimony." Jinro Am. Inc. v. Secure Investments, Inc., 266 F.3d 993, 1004 (9th Cir. 2001). "An expert witness–unlike other witnesses–is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation, so long as the expert's opinion [has] a reliable basis in the knowledge and experience of his discipline." Id. (citations and quotation marks omitted).

In Daubert, the Court also clarified that parties should not be "overly pessimistic about the

capabilities of the jury and of the adversary system generally." Daubert, 509 U.S. at 596. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. "The role of the Court is not to determine 'the correctness of the expert's conclusions but the soundness of his methodology.'" Great W. Air, LLC v. Cirrus Design Corporation, No. 2:16-CV-02656-JAD-EJY, 2019 WL 6529046, *3 (D. Nev. 2019). "The judge is supposed to screen the jury from unreliable nonsense opinions… [t]he district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury." Id. at 4.

b. Dr. Daniel Elliot's Testimony

i. Dr. Elliot's Opinions about Prolift and TVT Based On His Prior Publication

The Court finds that Dr. Elliott's opinions about Prolift and TVT mesh used for treating SUI and POP in women are admissible because they do not conflict with his previous publication. Defendant argues that Dr. Elliott published literature in 2019 expressing that high-quality evidence exists to support the idea that synthetic midurethral slings achieve excellent short-term outcomes, and that the ideal mesh pore size is large. (#196, at 4–5). Defendant asserts that Dr. Elliott testifies now, in this case, that polypropylene mesh should never be used to treat an SUI and that all synthetic midurethral mesh slings are unsafe. Id. Plaintiffs argue in response that the statements Ethicon points to in Dr. Elliott's 2019 publication do not contradict his position on the safety of mesh devices, and even if found contradictory, the adequate procedure is cross-examination. (#206, at 8–10).

The 2019 publication does state that there is quality evidence indicating excellent short-term outcomes and long-term efficacy. (#196-4, at 7). But the article also has a section called "[s]ituations to avoid synthetic midurethral sling placement" and explains that there "are contraindications to placement of urethral mesh, including patients undergoing… concomitant SUI surgery." Id. It also says that "the recent AUA guideline notes surgeons should consider avoiding mesh placement in patients at risk for poor wound healing" and that in those cases,

there are other options surgeons can use such as Burch retropubic colposuspension. Id. In Dr. Elliott's expert report, he says that the mesh used in the TVT device "should not be used in the pelvic floor because the risks of the device far outweigh the benefits of the device." (196-1, at 13). It seems that Dr. Elliott acknowledges that mesh surgeries can be efficacious, but also that there are risks associated with mesh surgeries under certain conditions. For example, in his report Dr. Elliott states that "the TVT device should not be implanted into the human body for use in the treatment of SUI" which is consistent with the publication where he states that "there are contraindications to placement of urethral mesh" for SUI surgery. (Id. at 27). Dr. Elliott's deposition also states that he believes all the mesh slings currently available in the market are unsafe and implies that his concern is about long-term follow-up satisfaction despite the many studies showing current satisfaction. (#196-8, at 10). Therefore, the Court rejects Defendant's argument that Dr. Elliott's current testimony contradicts his publication and will allow direct and cross-examination to flesh out the nuances of his opinion. Dr. Elliott may be wrong about mesh being hazardous, but that is not for the Court to decide. See Daubert, 509 U.S. at 595.

ii. Dr. Elliott's Opinions About Non-Synthetic Mesh Procedures as Safer Alternatives Than Prolift and TVT

1. Relevancy

Ethicon argues that Dr. Elliott's opinions about autologous slings and Burch colposuspension being safer alternatives than TVT for the surgical treatment of SUI, and his opinions that native tissue repairs like sacrocolpopexy and colporrhaphy are safer alternatives to Prolift for the surgical treatment of prolapse are irrelevant. (#196, at 6–7). Ethicon argues these opinions are irrelevant because they are about traditional *procedures* and not medical *devices* and thus these opinions cannot "inform the issue of whether an alternative design for a product exists." Id. at 7. Plaintiffs argue that regarding POP, the *design* of the mesh used in Prolift makes it less effective than the traditional procedures that do not use mesh, and that Ethicon knew that synthetic, non-absorbable mesh was more likely to cause complications. (#206, at 3). Regarding the TVT mesh, Plaintiffs argue that although Dr. Elliott notes in his deposition that the Burch procedure and autologous slings are not medical devices and it's like comparing "apples to oranges," the main

difference is between long-term data and short-term data. Id.

The Court is convinced by Defendant's argument that Dr. Elliott's referral to alternative procedures do not entail changing the design of Prolift or TVT, but rather he advocates eliminating them from SUI surgeries altogether "and utilizing a completely different surgical alternative." (#219, at 6). The Court finds that alternative procedures or surgeries do not inform the jury how Ethicon could have made Prolift or TVT devices *themselves* safer to avoid the complications being claimed here. Further, this opinion could cause the jury to confuse the issues or waste time. See Fed. R. Evid. 403.

Plaintiffs also argue that Dr. Elliott's opinions are relevant to Ethicon's failure to warn and will help the jury to decide whether Ethicon included sufficient warnings with the TVT and Prolift mesh kits because of all the data comparing traditional surgical procedures and medical devices using mesh. Id. at 5. "Under Nevada law, to prove a failure to warn claim, a plaintiff must show (1) the product had a defect which rendered it unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer, and (3) the defect caused the plaintiff's injury." Heinrich v. Ethicon, Inc., 455 F.Supp.3d 968, 972–73. "A product may be found unreasonably dangerous and defective if the manufacturer failed to provide an adequate warning." Id. A plaintiff must prove causation and can do so by "demonstrating that a different warning would have altered the way the plaintiff used the product or would have prompted plaintiff to take precautions to avoid the injury." Id. However, "[t]he medical device manufacturer… is not in the best position to weigh the risks and benefits or using the device in a particular patient." Id. at 974. "Rather, 'the physician is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment.'" Id.

There is also no way for Ethicon "to assess the suitability of its product for a particular patient in a particular situation" and there is no way for the manufacturer to "ensure that the patient receives the written warnings." Id. Especially because the traditional procedures Dr. Elliott prefers are not medical devices being implanted in bodies, failing to warn patients about an entirely separate medical procedure is irrelevant to whether Ethicon failed to warn patients about possible defects in Prolift or TVT. Therefore, Dr. Elliott may not testify specifically that

the traditional procedures would have been a safer alternative than Prolift or TVT under an alternative design theory.

2. Reliability

Ethicon argues that Dr. Elliott's opinion that a device with a lighter-weight and larger-pore mesh would have been safer than the mesh Prolift used is unreliable expert opinion. (#196, at 9). Ethicon argues that reference to a lighter mesh–Ultrapro, which was used in Prolift+M, should not be testified as a safer alternative because he does not indicate it as safer in his expert report or his deposition. Id. at 9–10. Dr. Elliott stated in his deposition that because Ultrapro was eventually put into Prolift+M it reinforced his opinion that "[m]esh should not be placed in the vagina." (#196-8, at 13). The Court finds that Dr. Elliott may not explicitly testify that Ultrapro mesh is a safer alternative, but he may testify generally about lighter-weight and larger-pore mesh being less likely to cause complications in the body. The Court determines that the medical literature Dr. Elliott relies on to support his decision is reliable. The Court also finds that Dr. Elliott has adequate experience and expertise to opine on this topic generally.

Dr. Elliott refers to many studies to support his conclusion that lighter-weight and larger-pore material is safer. (#196-1, at 22–23). Defendant argues that there are flaws in these studies. (#196 at 11–12). Defendant will have the opportunity to cross-examine Dr. Elliott about any weaknesses in these studies, feasibility issues, and FDA rejections of Ultrapro. Impeaching Dr. Elliott in front of a jury is the best solution for admissible but shaky evidence. See Daubert, 509 U.S. 579, at 596.

"If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." In re: Ethicon, Inc., MDL No. 2327, 2016 WL 4500766, at *4 (S.D.W.Va., Aug. 26, 2016). In this case, the witness is relying on scientific literature in addition to his experience, but regardless, the Court finds his experience is sufficient to justify an opinion on lighter-weight, larger-pore mesh as better. Part of Dr. Elliott's opinion is that the Prolene mesh used in Ethicon's devices is identical to the Prolene used in hernia mesh, and it performs poorly in the abdomen, it surely performs worse in the

vagina. (#206, at 7). Dr. Elliott is a specialist in urogynecology and has vast experience with SUI and POP, as well as the anatomical structure of the vagina. (#196-1, at 5). The Court finds his experience does bridge the gap to allow Dr. Elliott to opine about different types of mesh and how they interact with the vagina.

Finally, the Court is tasked only with screening the jury from nonsense opinions, and not with judging the validity of an expert's conclusions. See Great W. Air, LLC, 2019 WL 6529046, at *3. Therefore, Dr. Elliott's opinion testimony regarding the weight and pore size of mesh in surgery is admissible.

iii. Dr. Elliott's Opinions About Ethicon's Research and Testing, Physician Training, and Adverse Event Reports

Ethicon asks the Court to preclude Dr. Elliott from offering various opinions criticizing Ethicon for failing to meet their legal duties regarding research and testing, physician training, and adverse event reports because they are outside the scope of his expertise. (#196 at 18). Mrs. and Mr. Carter argue in response that his opinions do not cross the line into inadmissible expert opinion and that his opinions are "really just observations from a physician's perspective of undisputed facts[.]" (#206, at 10). However, the Court is unconvinced. Plaintiffs have not pointed to evidence that Dr. Elliott is qualified to opine on these topics. There is nothing in his background that would provide him with specialized knowledge about what testing Ethicon should have performed, as is stated in his expert report. (#196-2, at 14). Even with all the clinical experience Dr. Elliott has, he has never manufactured or worked on the design of a medical device.

Mrs. and Mr. Carter have not claimed that the implanting physician, Dr. Hsieh, improperly implanted the device in Mrs. Carter, thus Dr. Elliott is precluded from opining that Ethicon failed to properly train their physicians on implantation of their devices. See Heinrich v. Ethicon, o. 2:20-cv-00166-APG-VCF, 2021 WL 2285435, at *5 (D. Nev., June 4, 2021). There is also no evidence that Dr. Elliott is qualified to testify about Ethicon's physician training as he has never participated in any Prolift training. (#196-32, at 4).

Finally, Dr. Elliott has no relevant experience with the FDA or medical device industry that

would justify him offering expert testimony regarding the standard of care for collecting and reporting adverse events at Ethicon.

III. Conclusion

Accordingly, **IT IS HEREBY ORDERED** that Defendant's Motion to Limit Opinions of Daniel Elliott, M.D. (#196) is **GRANTED** in part and **DENIED** in part.

DATED this 30 day of September 2022.

Kent J. Dawson
United States District Judge